MTN-038
Overview of Data Collection and Management

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SCHARP

Seattle, WA

Outline

- What we will cover
  - Rave/PTID basics
  - Randomization
  - Form population dynamics
  - MTN038-specific forms
  - Where to find more information

MTN
microbicide trials network

Outline

- What we will not cover
  - CASI
  - Rave manual
  - Query management
  - CCGs
  - Atlas
  - SSPs

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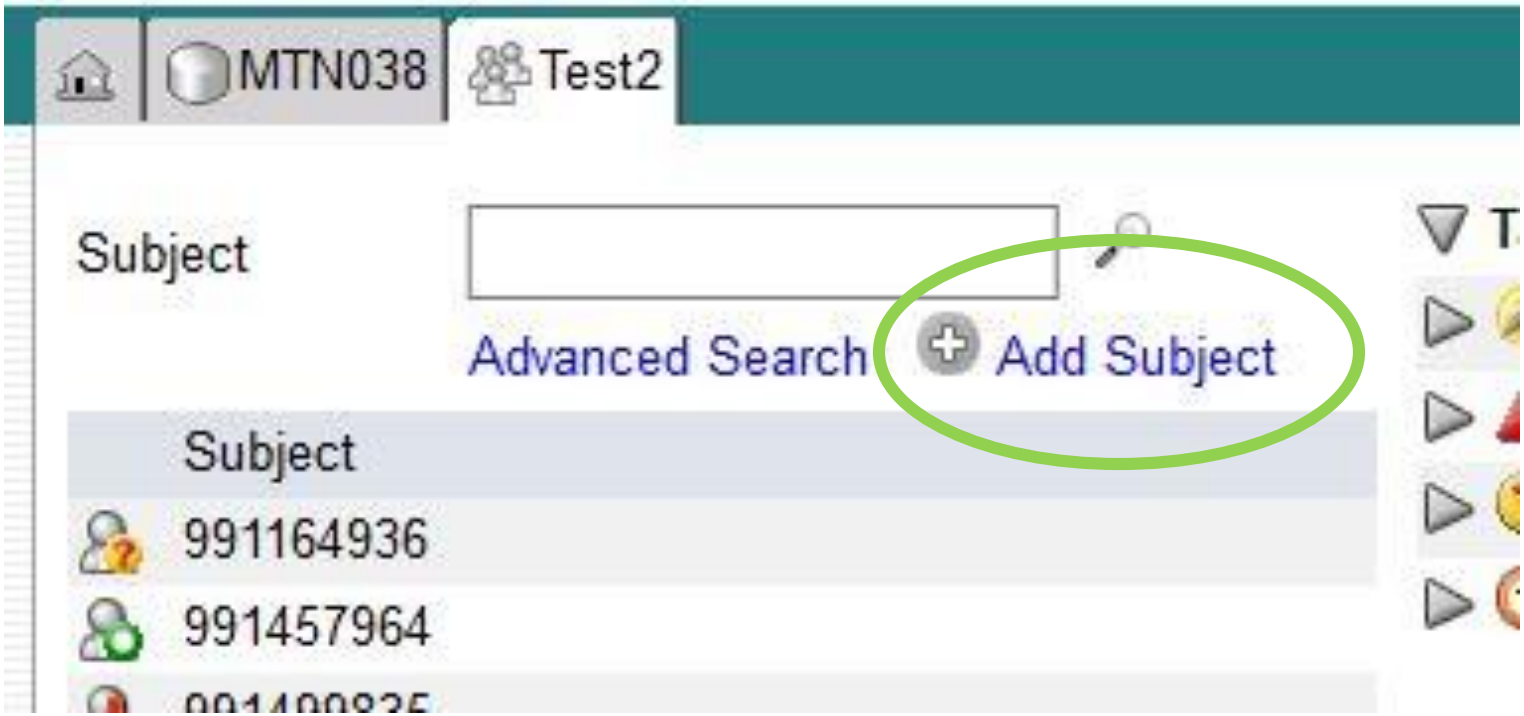
Rave/PTID Basics

- "Add Subject" generates a PTID



Rave/PTID Basics

- PTID structure

CRS Name	DAIDS ID	Rave ID
Birmingham	31788	821
Pittsburgh	1001	702
Bridge (SF)	30305	764

- Unique 9 digit identifier

XXX-YYYYYZ

Rave ID Ppt ID + check digit

Rave/PTID Basics

- The PTID-Name Linkage Log must be completed in real time. It is considered a source document for assigning PTIDs to participants.

	Participant ID	Name	Date ddMMMyy	Initials
1				
2				
3				
4				
5				
6				
7				

Rave/PTID Basics

- Direct data entry is strongly recommended. Site Data Management SOP should address data that will not be direct-entered.

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Randomization

- Approx. 48 participants will be randomized in a 2:1 ratio to either 1.4 g TFV IVR or to a placebo IVR.
- The timing of biopsies will also be randomly assigned.
  - Both of these randomizations take place within the database.
- In addition, approx. 24 participants will be randomly selected for In-Depth Interviews (IDIs).
- The randomization schemes will be generated and maintained by the MTN SDMC and specified in the MTN-038 SSP manual.

Randomization

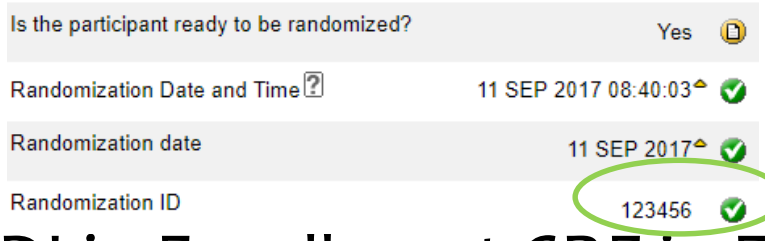
- Participants will be randomized to In-Depth Interviews (IDIs) outside of Medidata Balance.
  - MTN SDMC will provide separate IDI randomization lists to each site.
  - After treatment group and biopsy schedule randomization in Balance, use the Randomization ID to find the IDI group on the IDI randomization list.

Randomization ID	Consider for IDI
201	Yes
202	Yes
203	No
204	No
205	No
206	Yes
207	Yes
208	Yes
209	No
210	Yes
211	Yes
212	Yes
213	No
214	No
215	No
216	No
217	Yes
218	Yes
219	Yes
220	Yes
221	No
222	Yes
223	Yes
224	Yes

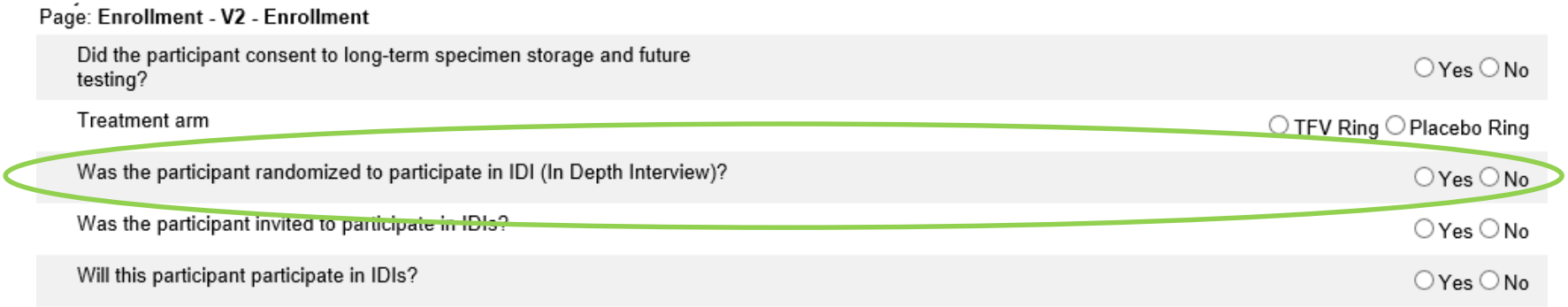
Example from MTN036

Randomization

- Document IDI Randomization on Enrollment CRF
  - Randomization ID can be found on the Randomization CRF in the Enrollment visit



  - Document IDI in Enrollment CRF in Enrollment Visit



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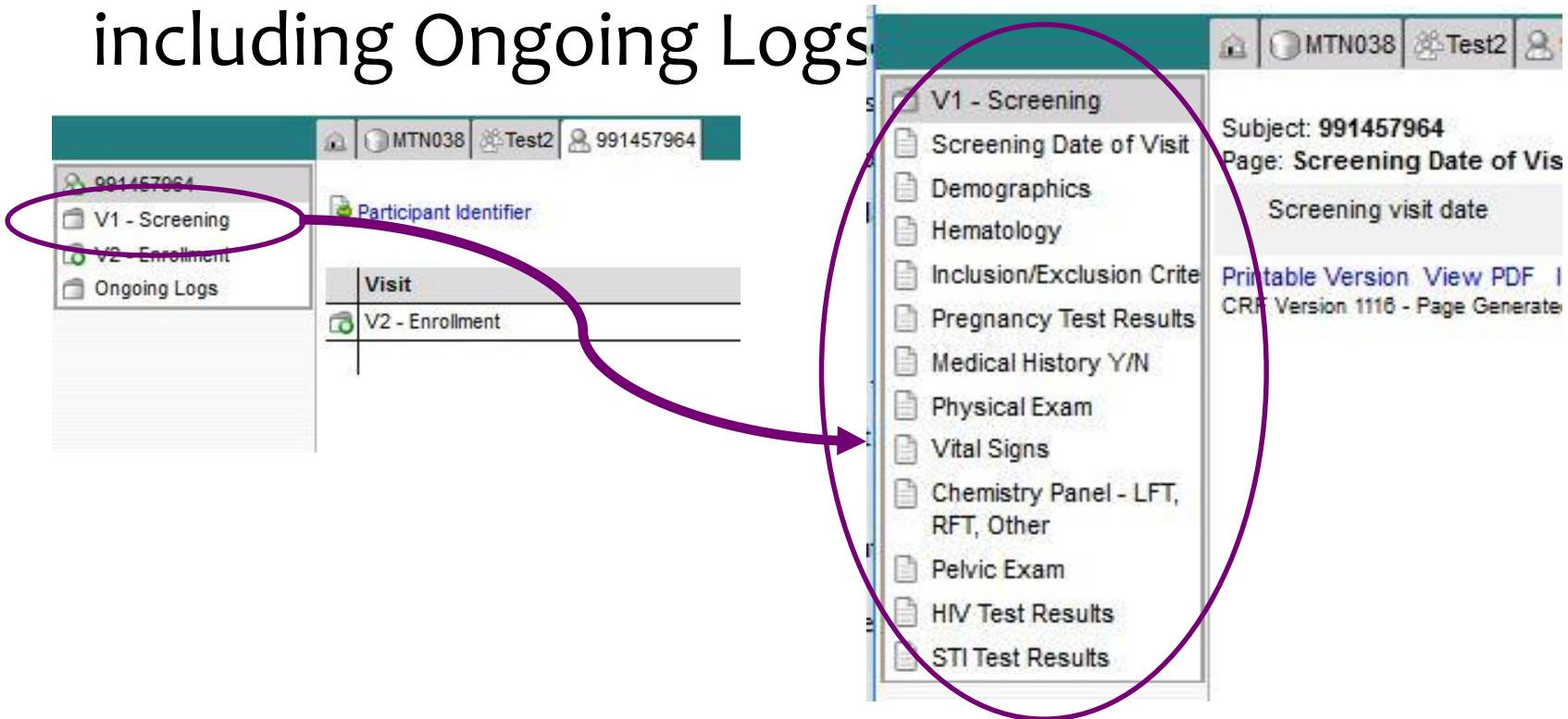
Form Population Dynamics

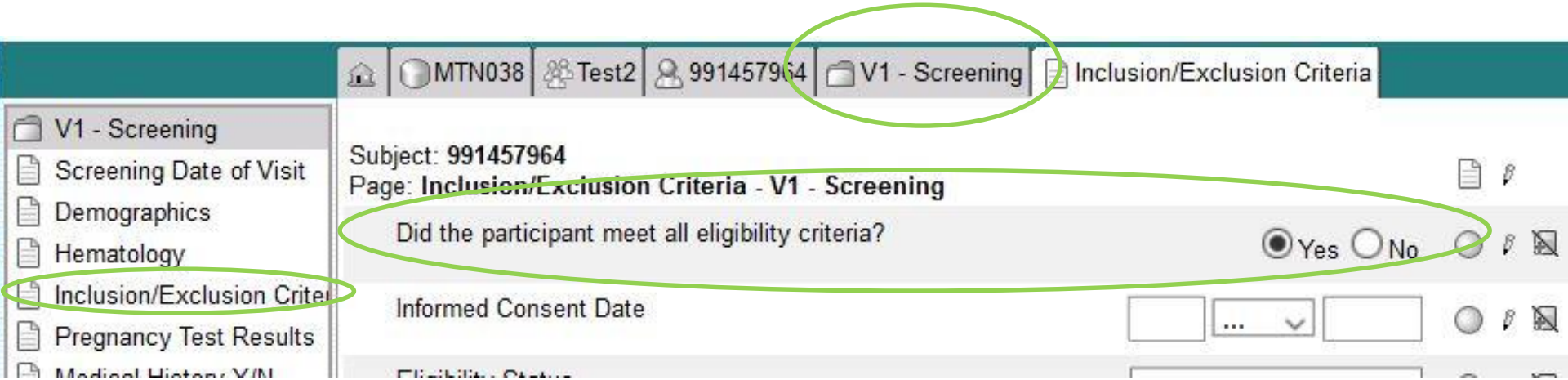
- When you assign a PTID, all forms for Screening and Enrollment are automatically generated within a participant's visit folder, including Ongoing Logs



Form Population Dynamics

- In order to populate the remaining visit folders for each participant:

  1) In the V1 - Screening folder, on the Inclusion/Exclusion Criteria form, click "Yes", in response to "Did the participant meet all eligibility criteria?"



Form Population Dynamics

- In order to populate the remaining visit folders for each participant:

  2) …and in the Enrollment folder, on the Randomization form, click "yes" on "Is the participant ready to be randomized?" Click "save", and all the remaining visit folders will populate.

Form Population Dynamics

- Regardless of whether or not a participant ultimately enrolls, please complete the Inclusion Exclusion Criteria and Demographics forms in the Screening folder for everyone who signs a consent form.

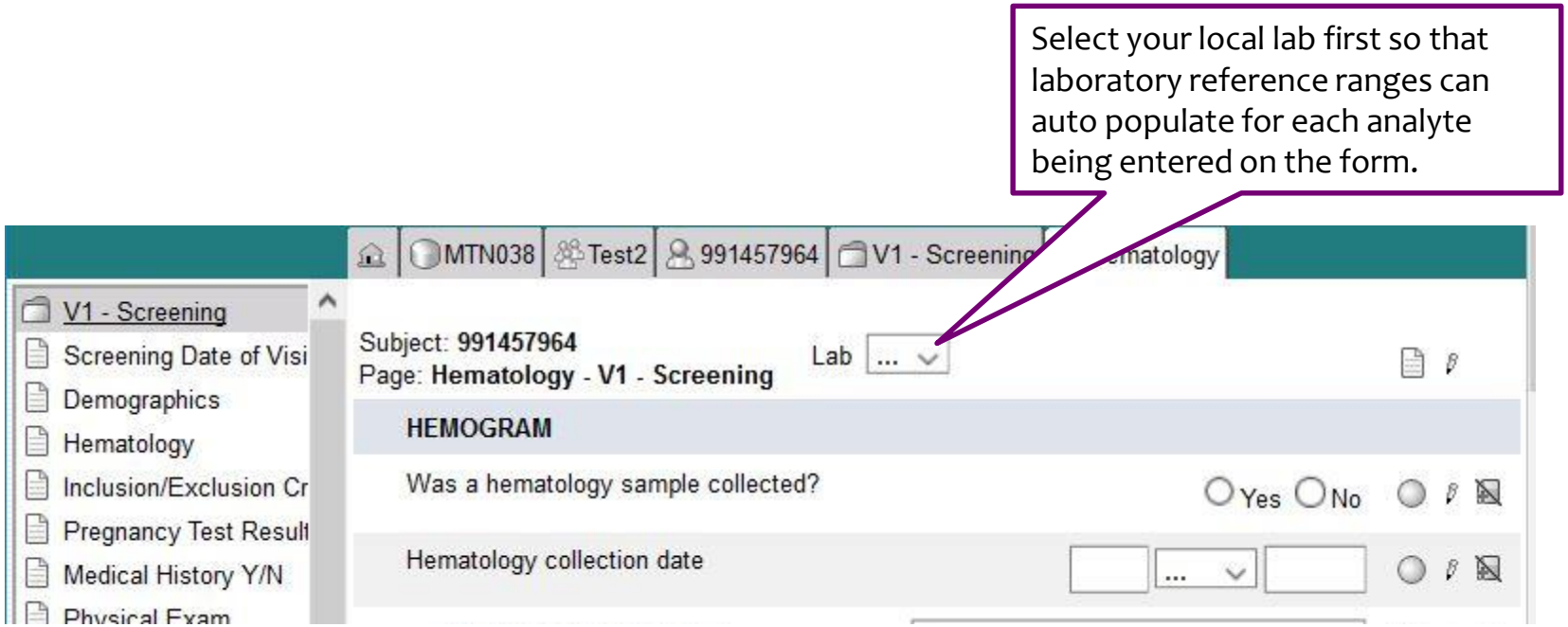
Form Population Dynamics

- For every follow-up visit (V3-10), the "Follow-Up YN" form needs to be completed in order to populate the remainder of the forms for that visit.

- It is now standard for YN CRFs to populate their respective CRFs
  - this is a change! – used to have summary forms, now you need to fill out the YN form first
- Once a particular YN CRF has been completed with "Yes", the respective CRF will populate for subsequent visits

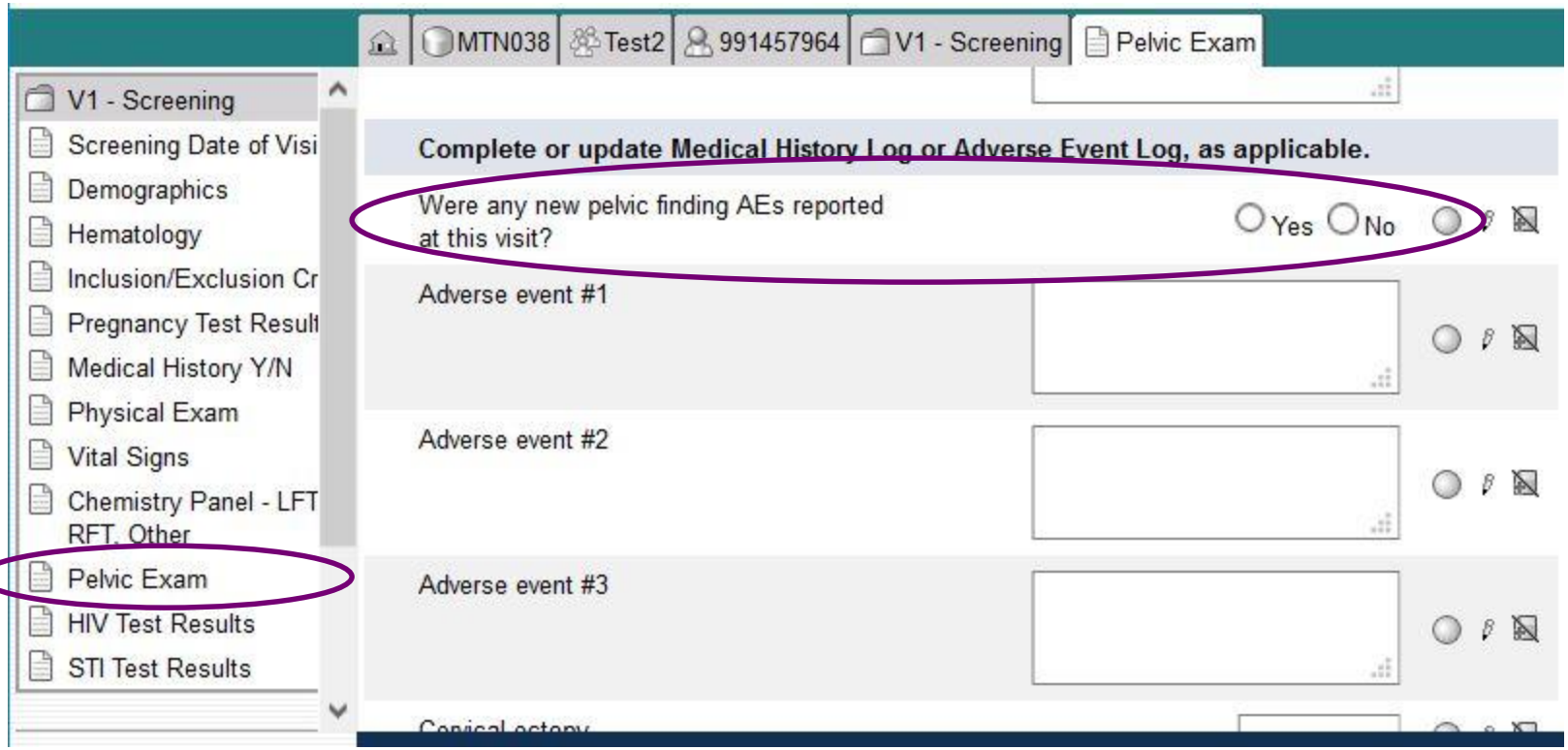
Form Population Dynamics

- The Demographics CRF you complete at Screening uses calculated age and other data to populate the lab module in Medidata.
- In Chemistry and Hematology CRFs, select lab FIRST:



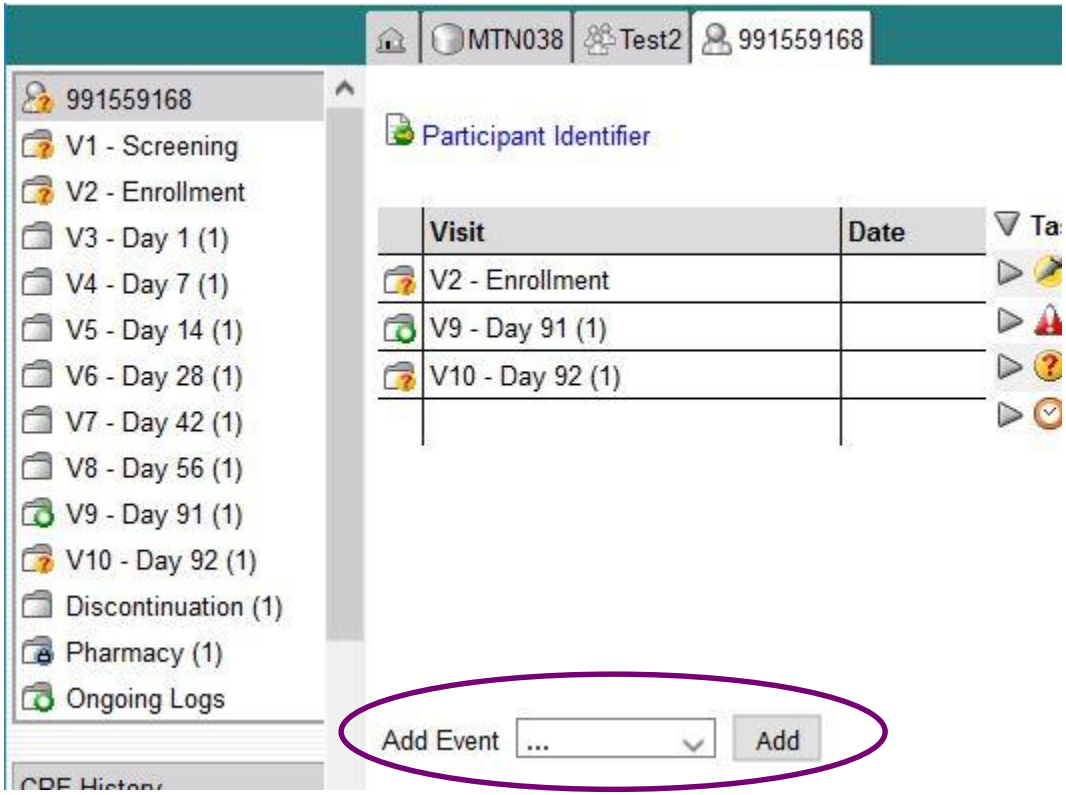
Form Population Dynamics

- Screening Forms
  - No AEs expected at Screening or Enrollment



Form Population Dynamics

- To Add Pregnancy & Interim visits
  - Find the "Add Event" dropdown menu
  - Menu located at the bottom of the ppt "home" page



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MTN-038-specific forms

- PK Endpoints (Primary)
  - TFV concentrations in plasma
  - TFV concentrations in CVF
  - TFV concentrations in rectal fluid
  - TFV and TFV-DP concentrations in cervical tissue
  - Particular attention to timed specimen CRFs
    - Timed cervical specimen storage at enrollment (v2.0) and v9.0
    - Timed specimen storage at PUEV/v9 when ring is removed
    - Timed versions will supplant the "normal" forms

MTN-038-specific forms

- Safety Endpoints (Primary)
  - "The proportion of participants with Grade 2 or higher genitourinary adverse event"
  - "The proportion of participants with Grade 3 or higher adverse event"

MTN-038-specific forms

- Secondary Endpoints
  - Frequency of study IVR removal/expulsions
  - IVR use initiation and persistence
  - Degree to which study participants liked or disliked using the IVR

MTN-038-specific forms

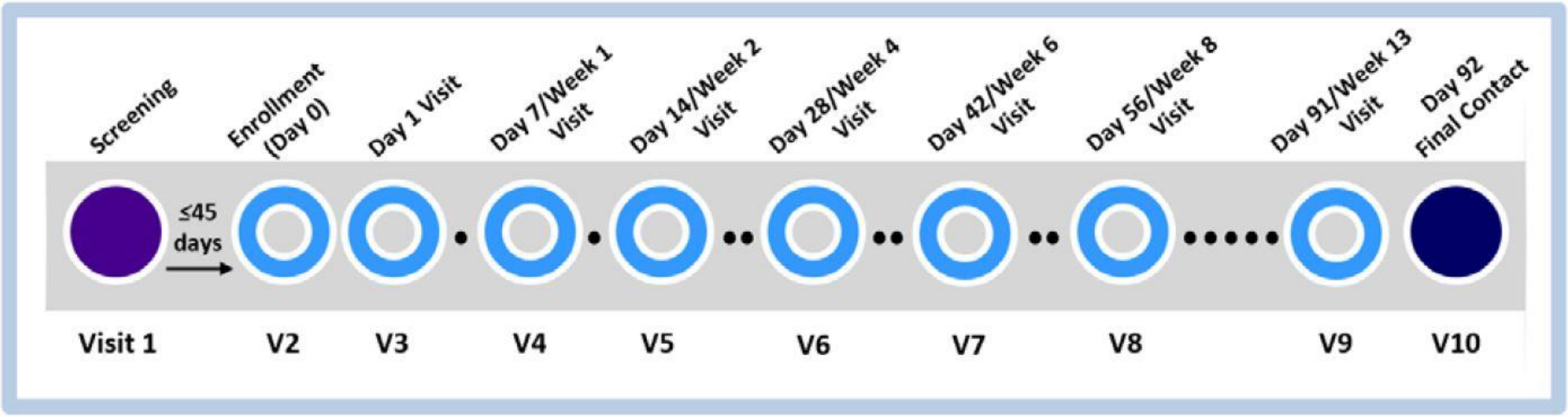
- Adverse Event (AE) Data
  - Report only one diagnosis, symptom or sign per page
    - Record unifying diagnosis whenever possible
  - Avoid using abbreviations
  - Review for correct spelling
    - Variations in spelling can lead to differences in AE coding, so similar AEs will appear differently in AE safety reports
  - Do not report surgeries as AEs (these are treatments)

MTN-038-specific forms

- Adverse Event (AE) Data
  - Report ASAP, no later than 3 days following awareness
  - severity grading per usual
  - relationship to study product per usual
  - Action taken w/ study product per usual
  - SAE or EAE reporting per usual

MTN-038-specific forms

- Visit Windows



- All enrollment procedures must occur on the same day.
- The participant's menstrual cycle must be considered when scheduling Visit 2-Enrollment (Day 0). Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-4 (Days 0, 1, and 7).
- IVR provided at Visit 2, and collected at Visit 9.
- Participants will be randomized to provide cervical tissue samples at either Visits 5 and 8 (Days 14 and 56) or at Visits 6 and 9 (Days 28 and 91).

MTN-038-specific forms

- Visit Windows

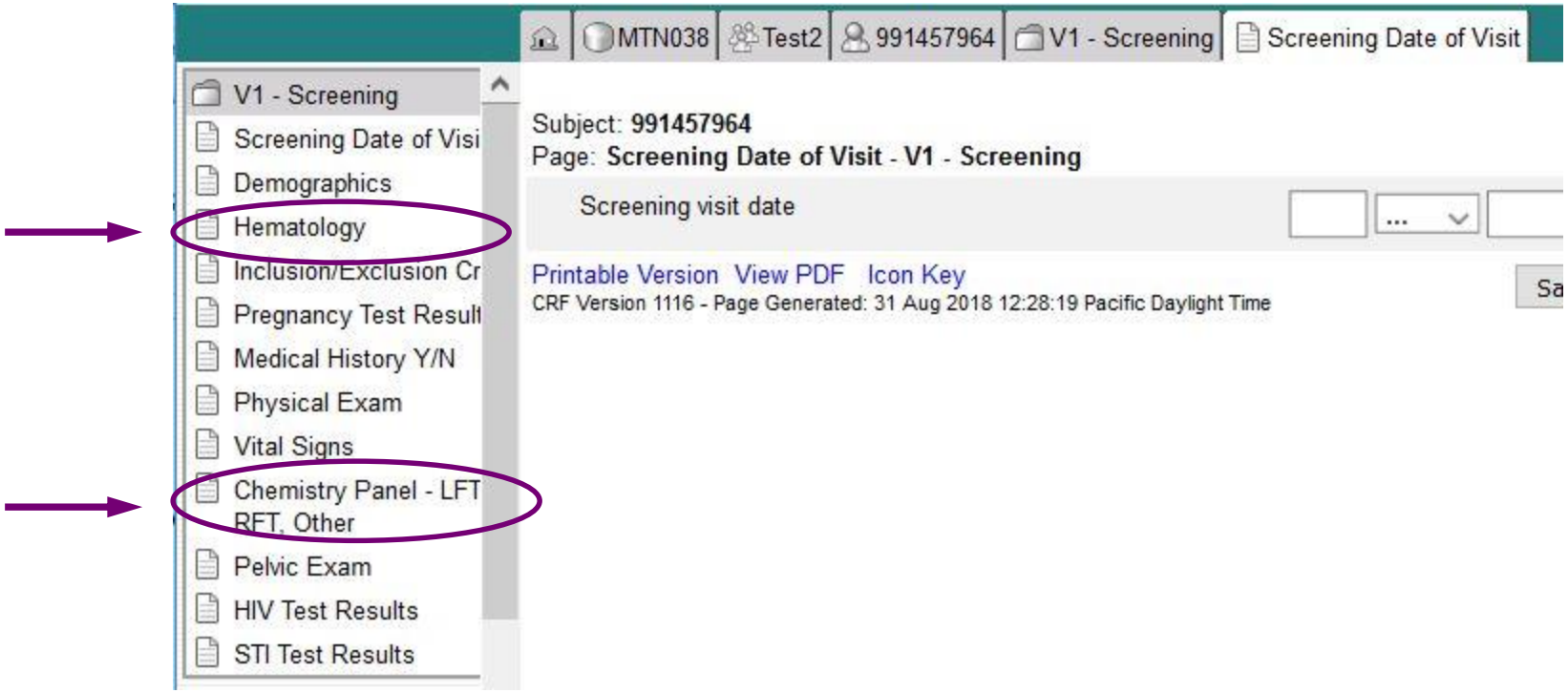
MTN-038 Visit Windows

All windows are in days.

Visit	Visit Code	Target Day	Window Opens	Window Closes	Visit Window Length
Screening	1.0	NA	≤ 45 days prior to Enrollment		NA
Visit 2 - Enrollment (Day 0)	2.0	0	NA	45 days after Screening Visit	45 days
Visit 3 - Day 1	3.0	1	1	1	1 day (Target only)
Visit 4 Day 7/Week 1	4.0	7	6	8	3 days (Target +/- 1)
Visit 5 Day 14/Week 2	5.0	14	12	16	5 days (Target +/- 2)
Visit 6 Day 28/Week 4	6.0	28	25	31	7 days (Target +/- 3)
Visit 7 Day 42/Week 6	7.0	42	39	45	7 days (Target +/- 3)
Visit 8 Day 56/Week 8	8.0	56	53	59	7 days (Target +/- 3)
Visit 9 Day 91/Week 13	9.0	91	89	93	5 days (Target +/- 2)
Visit 10 Day 92/Final Contact	10.0	92	24 - 72 hours after PUEV (Visit 9)		3 days (Target + 2)

MTN-038-specific forms

- "Local Labs" CRFs changed to CHEM and HEME



MTN-038-specific forms

Split Visits

- A visit is a split visit when the required visit procedures are split (done) over 2 or more days
- The days must *all* fall within allowable visit window; any required procedures not done within allowable window are missed
- For split visits, only 1 Follow-up Visit Summary eCRF is completed, and the Visit Date on this CRF is the date of the first part of the split visit
  - All CRFs completed for the split visit within the applicable study visit folder (e.g., CRFs completed for a split Visit 6 across Days 27 and 28 would all have visit code 6.0)

MTN-038-specific forms

Interim Visits

- Visits that take place between scheduled visits
  - Additional study procedures and/or data collection conducted outside of what is specified in protocol for required study visit (Example: Report of new AE, issue with study product, etc.)
  - Required study visit procedures conducted outside visit window, either to make up certain procedures from missed visit or conduct Visit 9 Early Termination Visit procedures due to early product discontinuation
- All interim contacts (e.g., phone calls and/or clinic visits) will be properly documented in study files and on applicable CRFs

MTN-038-specific forms

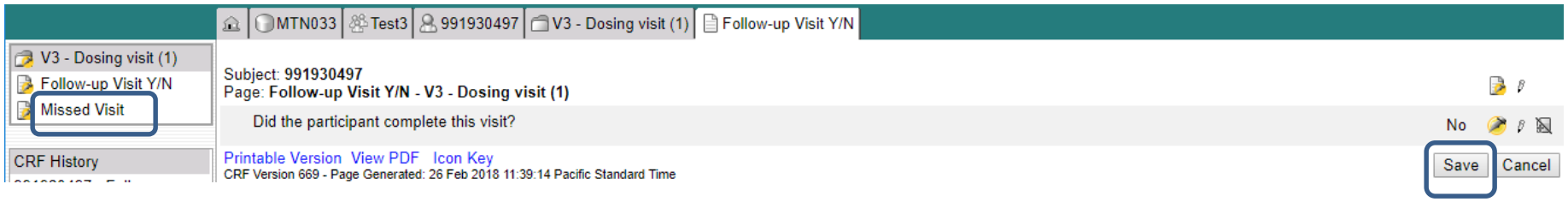
Missed Visits

- A visit is missed when:
  - No part of a visit is conducted within the allowable visit window, OR,
  - A visit does not have a window, and the participant cannot come in on target day.
    - For 038, the visit that meets this definition is Visit 3.
- Missed visits are not made up. Rather, sites should make every attempt to retain participants at future visits.

MTN-038-specific forms

If a participant does miss a visit:

- Document in the database using the Missed Visit CRF
- The Missed Visit form will let SCHARP know not to expect any other forms for that participant at that study visit (with the exception of the Follow-up Yes/No CRF).
- The Missed Visit CRF is completed in lieu of a Protocol Deviations Log CRF



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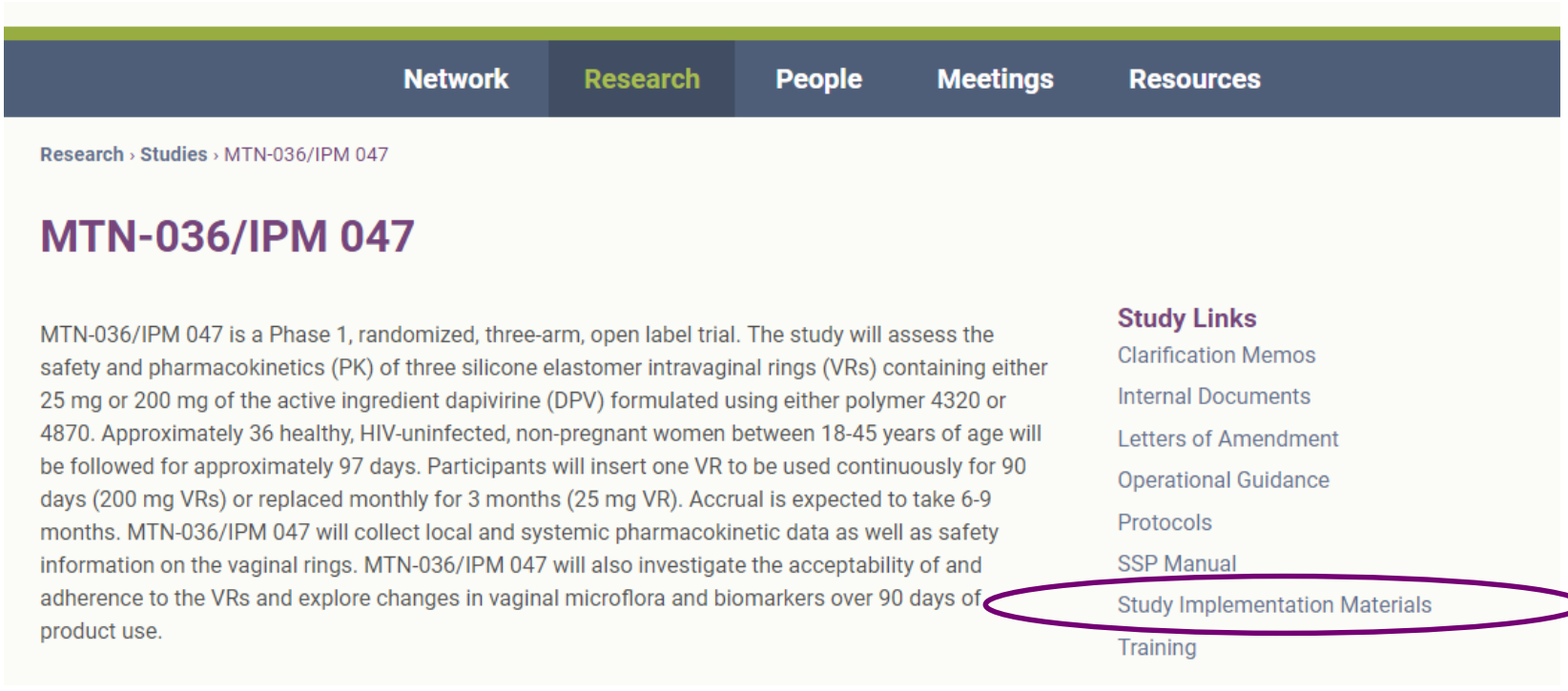
Where to find more information

- CRF Completion Guidelines (CCGs) to aid in form completion will be available on the MTN-038 ATLAS webpage
- Help text available on select items within Rave to provide key guidance on form completion
- Site Specific Procedures (SSPs) will also provide data-related guidance.

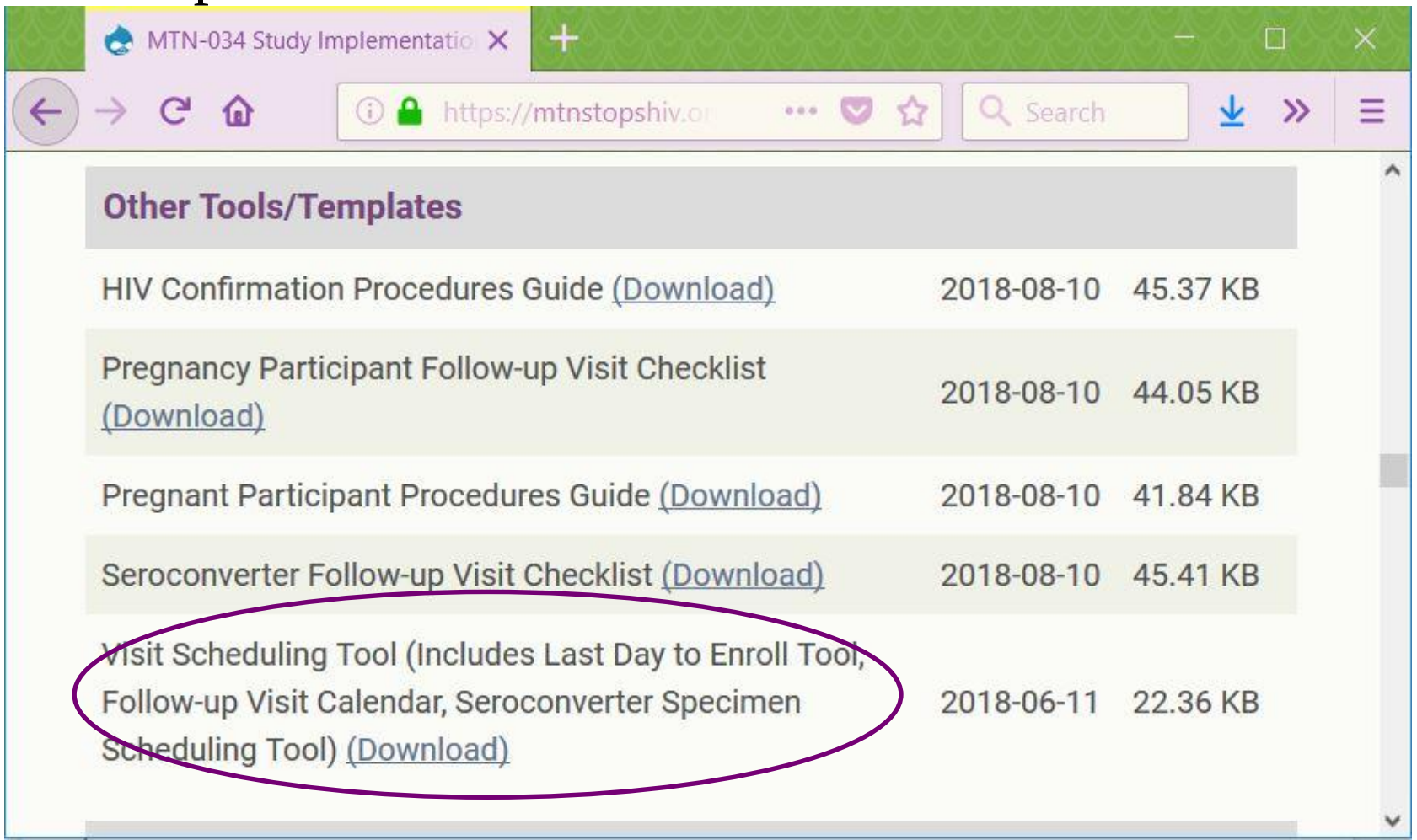
Where to find more information

- Last Day to Enroll calendar tool
  - *Will* be available on study website
  - https://mtnstopshiv.org/research/studies/mtn-038
  - Example from MTN 036



Where to find more information

- Example from MTN034



F1

MTN-034 - Calculation of Last Possible Day to Enroll

Screening Visit Date: *Date Screening Consent marked or signed*	**Monday, January 8, 2018**
	Enter as dd-mmm-yy
Date participant initiates effective method of contraception:	**Wednesday, January 10, 2018**
	Enter as dd-mmm-yy
First possible Enrolment date based on initiation of effective method of contraception:	**Sunday, March 11, 2018**
	Shown as dd-mmm-yy
Last Day to Enroll:	**Monday, March 19, 2018**

Instructions:

1. Enter Screeni
order to generat
the participant c
REACH.

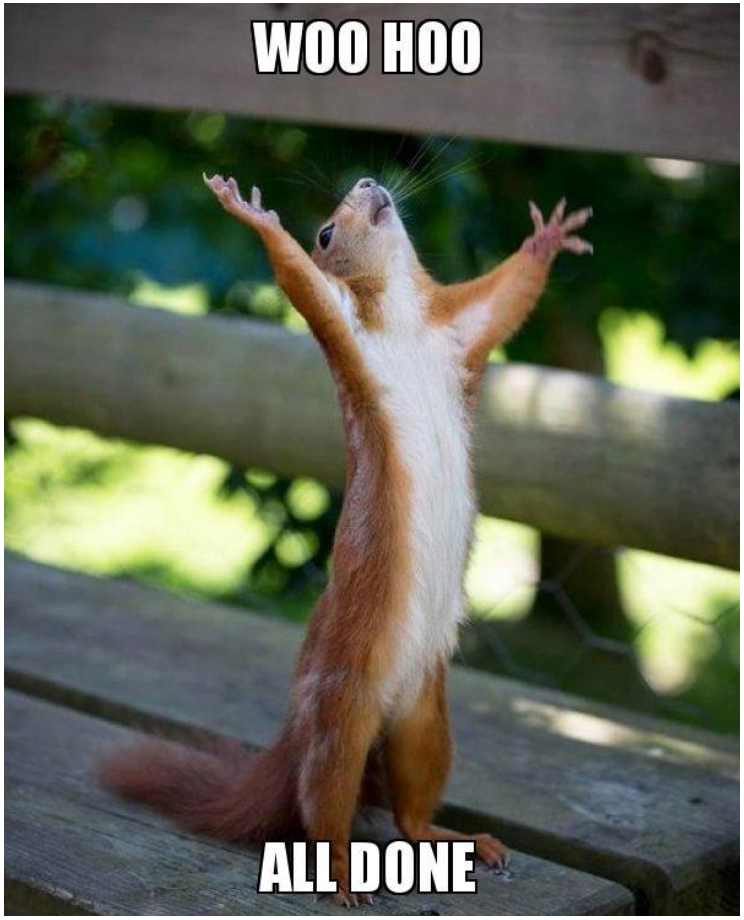
2. Enter the date
participant initiat
method of contra
generate the firs
that the partiicpa
enrolled based o
criteria #9. Do n
participant prior

*Per inclusion criter
must use an effe
contraception for a
prior to En*

Where to find more information

- For non-protocol specific overviews:
  - https://mtnstopshiv.org/research/studies/mtn-020/study-implementation-materials/clinical-research-training
- For Medidata RAVE:
  - www.imedidata.com
- For help with ATLAS:
  - https://atlas.scharp.org/

Questions?



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